



STANDARDS AND CONFORMITY ASSESSMENT

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South Korea Standards and Conformity Assessment System

Overview

The Korean Government adopted the ISO 9000 system (modified as the KSA 9000) as the official standard system in April 1992 and published related regulations in September 1993. In 1997, Korean companies also adopted the ISO 14000 environment management system.

However, there are still concerns over Korea's implementation of the commitments that were made when the GATT Agreement on Technical Barriers to Trade (the "Standards Code") was signed in 1980. Korea seems to develop standards that effectively block imported goods by affecting only imported goods or which are not applied in an equal manner to domestic products. In addition, the Korean government sometimes issues new regulations without adequate public consultation procedures. The absence of a comment period and adequate time for industries to adjust can be a significant barrier to trade. Finally, implementation periods sometimes do not give foreign exporters sufficient time to comply, which often leads to unnecessary and costly interruptions in trade. In light of the fact that Korean firms consider compliance with the ISO 9000 necessary to compete in international markets, the Korean government has indicated that it will address such problems and reduce barriers.

The Korean Agency for Technology and Standards (KATS), under the Ministry of Commerce, Industry and Energy (MOCIE), is undertaking a program to make Korean standards consistent with international standards. Stronger recognition of this necessity has developed from the need to protect global consumers (i.e. electrical products safety), to facilitate trade for small and medium sized Korean companies, to increase overall efficiency of production as well as limit unnecessary barriers to legitimate trade. The Korean Industrial Standardization Act requires 60 days' notice before implementing new standards. Whenever there is a change in standards, the government is required to notify the WTO's Committee on Technical Barriers to Trade (TBT).

The Korean Food and Drug Administration (KFDA) generally accepts internationally accepted standards, or equivalents, of advanced countries or consensus standards. Included in this list of standards recognized by Korea are those of the International Standard Organizations (ISO), the American Society for Testing and Materials (ASTM), the International Electro-technical Commission (IEC), the U.S. Pharmacopoeia (USP), the British Pharmacopoeia (BP), the European Pharmacopoeia (EP), and the Japanese Pharmacopoeia (JP).

Korea has reduced some barriers in the automotive industry. The Korean government has promised not only to lower Korea's WTO tariffs on motor vehicles and actively participate in future multilateral tariff reduction negotiations, but also to change standards and certification procedures that increase costs and cause delays to market entry due to excessive



STANDARDS AND CONFORMITY ASSESSMENT

Excerpt From Country Commercial Guide

Trade.gov/standards

documentation and testing. In October 20, 1998, the U.S. and Korea signed an MOU for improved market access for U.S. and other foreign motor vehicles into the Korean market.

Although the MOU was targeted at ongoing government efforts to improve public perceptions of imports, mainly by preventing discriminatory procedures and promoting benefits of open trade and competition, the most useful outcome of the MOU was the self-certification system granted to U.S. manufacturers in 2002. This agreement made Korea the third country, after the U.S. and Canada, to introduce a self-certification system in the industry.

Despite selected improvements, however, some Korean standards are still inconsistent with international standards, and a lack of clear standards guidelines persists. KFDA has established standards for only 76 of its 950 device classifications. These few standards serve as the lower limit criteria for product approval. With many KFDA standards yet to be established, a product may meet other non-KFDA standards but not fit into KFDA's existing standards, causing delays in some cases.

U.S. companies have often faced difficulties due to rejection of equivalent standards in Korea, particularly for food, nutritional products, cosmetics, pharmaceuticals, medical devices and electronic products.

Details regarding standards and import regulations for food and agricultural products can be found in on Foreign Agricultural Service website in the [Food and Agricultural Import Regulations and Standards](#) (FAIRS) report for Korea.

For standards contact information, go to the link below:
<http://www.buyusa.gov/korea/en/standardscontacts.html>

Standards Organizations

The Korean Agency for Technology and Standards (KATS), under the Ministry of Commerce, Industry and Energy (MOCIE), develops standards for capital goods, including construction materials and consumer products, as well as products for logistics operations.

The development of standards and unification of Korean Standards (KS) with other government regulations under KATS' jurisdiction. The agency consults with other private organizations to develop standards and certifications. Every five years, KATS reviews KS to validate, revise or withdraw standards depending on the needs of industry. KATS may make adjustments in KS between five-year intervals to ensure conformance with international standards or to facilitate the development of new technologies. KS are then established by consensus with the Korean Industrial Standards Council (KISC). KISC members are technical experts from industry, academia, R&D organizations and consumer groups. They review and decide on KS standards as well as on

Korea's acceptance of international standards. KISC currently consists of 39 division



STANDARDS AND CONFORMITY ASSESSMENT

Excerpt From Country Commercial Guide

Trade.gov/standards

councils of 300 members, supported by 594 technical committees with 6,808 members. The Korean Food and Drug Administration (KFDA), similar to its counterpart in the U.S., sets standards for research, new product evaluation, test method development, product monitoring for food and drugs as well as radiation safety regulations that apply to all radiation-emitting devices distributed within Korea.

The [Telecommunications Technology Association \(TTA\)](#) covers telecommunications, information technology, radio communications and broadcasting. The Association establishes industry standards and has been instrumental in creating the current Korean Information and Communication Standards. With the opening of an IT Testing Laboratory in December 2001, TTA has been able to provide a one-stop service center; from the establishment of IT standards to the testing and certification for IT standards products. TTA also collaborates with international and national standards organizations such as ITU, ETSI, T1, TTC, ARIB, TSACC, ACIF and etc.

Conformity Assessment

KATS establishes guidelines for government and private sector institutes to perform reliability assessment and certification. It also performs market surveillance on KS-marked products and penalizes products that do not meet KS requirements.

Korea has a fairly extensive regulatory system for biotechnology products. The Ministry of Agriculture & Forestry (MAF) regulates labeling of unprocessed biotech products and conducts environmental risk assessments (ERAs) of biotech crops. The Korea Food & Drug Administration (KFDA) regulates food safety approval of biotech crops and labeling of processed food products containing biotech components.

The National Plant Quarantine Service conducts post-entry quarantine inspection of plants and plant products. It was designated as an independent agency in 2001 and is affiliated with the Ministry of Agriculture and Forestry. Ministry of Health and Welfare (MOHW) regulates products are required to have locally based (pharmacists/chemists/Korean pharmaceutical trade associations/etc.) tests on every

batch of all shipments. Products tested outside Korea are frequently not accepted.

Products requiring Electro Magnetic Interference (EMI) product testing must be done by government-approved testing companies. Modems and monitors require homologation approval even if already approved in the country of origin.

The Korea Toy Industry Cooperative (KTIC) Inspection Team tests moving toys. Currently it is the only officially designated toy-testing agency. The Cooperative was incorporated in 1967 as a national nonprofit organization for toy manufacturers and traders.

The Korea Environment & Merchandise Testing Institute (KEMTI) (formerly the Korea Merchandise Testing & Research Institute – KOMTRI) has been accredited under the Korea Laboratory Accreditation Scheme (KOLAS) for tests covering hardline products, footwear,



STANDARDS AND CONFORMITY ASSESSMENT

Excerpt From Country Commercial Guide

Trade.gov/standards

textiles, packaging and testing equipment. This qualification is granted only to laboratories that meet certain quality and technical laboratory requirements based on ISO 17025.

The Korea Testing & Research Institute for Chemical Industry (KOTRIC), Quality Assurance Department, tests batteries, tires and safety glasses. It was accredited under the Korea Laboratory Accreditation Scheme in 1994. KOTRIC is an affiliated institute under the Ministry of Commerce, Industry and Energy.

The Korea Machinery-Meter and Petrochemical Testing & Research Institute (MPI), Quality Assurance Team, tests motor brake fluids, engine coolants and washer fluids. It was designated as a KOLAS institute in 1994.

The Fabric Inspection Testing Institute (FITI) - Testing & Research Institute tests fabrics. It was designated as a reliability assessment organization by MOCIE in 2001 and is accredited by KOLAS for a range of tests.

In terms of new legislation, the Ministry of Commerce, Industry and Energy's Living Modified Organism (LMO) Act is Korea's legislative response to the implementation of the Cartagena Bio-Safety Protocol (BSP). Environmental risk assessments for biotechnology crops will become mandatory. Several applications have already been submitted, however, none have yet been completed. The assessments will be similar to food safety assessments for biotechnology crops for human consumption. The U.S. Government is urging Korea to adopt a sufficient grace period and minimize restrictive measures to avoid major trade interruptions. Additionally, Korea is required to notify the World Trade Organization (WTO) of any new revised requirements.

Product Certification

Generally, private industrial organizations oversee import certification procedures. KATS, however, also issues certification marks for new technologies and recognizes quality products manufactured by Korean companies mainly to promote exports. The Korea Standards Quality Certification Association offers consulting advice and preparation for ISO9000, ISO14000, KS, TS16949, HACCP, UL, and CE.

In the spring of 2001, Korea began requiring ruminant exports to be certified as BSE-free by the U.S. government. As this requirement proved highly restrictive, it was resolved for pharmaceutical products. After an extensive legal review, the Korean government decided to accept BSE-free certifications by governments, manufacturers, and relevant suppliers.

After the discovery of a BSE-infected cow in the U.S. in December 2003, however, imports of ruminant products and poultry meal from countries with a history of BSE cases are highly restricted.

A number of Korea's sanitary and phytosanitary certification requirements continue to limit market access for a variety of imported products. However, progress was made in market



STANDARDS AND CONFORMITY ASSESSMENT

Excerpt From Country Commercial Guide

Trade.gov/standards

access for cherries. In April 2003, after lengthy consultations, the Ministry of Agriculture and Forestry ruled that all varieties of cherries would be permitted to enter Korea under certain conditions. Yet market access for in-shell walnuts is still hampered by a requirement for preexport clearance by MAF inspectors in the country of origin. Mutual Recognition Agreements (MRAs) with U.S. Organizations Korea is a member of the ANSI – RAB (American National Standards Institute-Registrar Accreditation Board) Multilateral Recognition Agreement.

Accreditation

Established in December 1992, the Korea Laboratory Accreditation Scheme (KOLAS) is the government accreditation body under the KATS Department of Technology and Standards Planning. KOLAS signed the Asia-Pacific Laboratory Accreditation Cooperation Multilateral Recognition Agreement (MRA) for testing in 1998 and for calibration in 2001. In 2000, KOLAS also signed the International Laboratory Accreditation Cooperation Multilateral Recognition Agreement on testing and calibration. As a result, tests that are done in laboratories of ILAC member countries are mutually recognized by 44 members economies. There are local testing laboratories authorized to certify firms under the ISO 9000 system.

As Korea has joined the International Accreditation Forum-Multilateral Recognition Arrangement (IAF-MLA), local certification for the ISO 9000 system is recognized in the 27 member countries of the IAF-MLA.

Technical Regulations

Revised or new standards or technical regulations are published by the Korean Agency for Technology and Standards (KATS) and made available on their website at http://www.ats.go.kr/fm_03/pyojun.asp. The articles, more frequently than not, are published only in Korean. All proposed or newly revised/established technical regulations are consolidated at this site.

Proposed revisions or establishment of regulations in Korean are made to the Director of Technical Regulations via the website at www.ats.go.kr. A public meeting consisting of lawmakers as well as relevant private/public industry organizations is held to comment on proposed regulations. Contact the [U.S. Embassy, Commercial Section](#) for assistance with revised or new standards.

Labeling and Marking



STANDARDS AND CONFORMITY ASSESSMENT

Excerpt From Country Commercial Guide

Trade.gov/standards

Country of origin labeling is required for commercial shipments entering Korea. The Korean Customs Service (KCS) publishes a list of the country of origin labeling requirements by Harmonized System Code number. Click "[Country of Origin](#)" for more information on markings.

Further labeling and marking requirements for specific products, such as pharmaceutical and food products, are covered by specific regulations from the Korean Government agencies responsible for these items. Korean language labels, except for country of origin markings that must be shown at the time of customs clearance, can be attached locally on products in the bonded area either before or after clearance. The Korea Food & Drug Administration (KFDA) is responsible for setting and enforcing Korean labels for food products other than livestock products. The Ministry of Agriculture and Forestry (MAF) regulates livestock products. The MAF also has its own set of standards for markings for the country of origin labeling of agricultural products. Local importers usually print Korean language labels when imported quantities are not large and consult with KCS about where they can be attached to the product.

For pharmaceuticals, all imported containers and packages must be conspicuously marked to show:

- 1) country of origin and manufacturer's and importer's names and addresses;
- 2) name of product;
- 3) date of production and batch number;
- 4) names and weights of ingredients;
- 5) quantity;
- 6) number of units;
- 7) storage method;
- 8) distribution validity date;
- 9) instructions for use;
- 10) import license number;
- 11) effectiveness;
- 12) import price and suggested retail price.

Details regarding labeling and marking regulations for food and agricultural products can be found in on Foreign Agricultural Service website in the [Food and Agricultural Import Regulations and Standards](#) (FAIRS) report for Korea.

Contact Information

Korean Agency for Technology and Standards (KATS)



STANDARDS AND CONFORMITY ASSESSMENT

Excerpt From Country Commercial Guide

Trade.gov/standards

www.ats.go.kr

Published technical regulations and standards

http://www.ats.go.kr/fm_03/pyojun.asp

Korean Food and Drug Administration (KFDA)

<http://www.kfda.go.kr/>

Korean Laboratory Accreditation Scheme (KOLAS)

www.kolas.go.kr

Local Standards Contacts

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Trade Agreements

The Republic of Korea is a member of the Asia-Pacific Economic Cooperation (APEC) forum. One goal of APEC, as outlined in its 1994 declaration, is to establish a Free Trade Area among its member countries by the year 2020. Substantive principles of the APEC forum include investment liberalization, tariff reduction, deregulation, government procurement, and strengthening IPR protection. Korea is the host country for APEC in 2005.

Korea has ratified Free Trade Agreements (FTAs) with Chile and Singapore. It has signed, but not yet ratified, an FTA with The European Free Trade Association (Norway, Switzerland, Iceland and Liechtenstein).

Korea has signed a framework agreement with the Association of South East Asian Nations (ASEAN) that will lead to an FTA in goods by the end of 2006 and other areas by the end of 2008. Korea is in the midst of FTA negotiations with Japan and Canada, and in discussion with the U.S. over whether or not to negotiate an FTA.

The Republic of Korea is a member of the World Trade Organization (WTO) and has signed subsidiary agreements including TRIPs (Trade Related Aspects of Intellectual Property) and the Government Procurement Agreement. Korea has been a member of the Organization for Economic Cooperation and Development (OECD) since December 1996.

Web Resources

U.S. Agricultural Trade Office- Seoul



STANDARDS AND CONFORMITY ASSESSMENT

Excerpt From Country Commercial Guide

Trade.gov/standards

www.atoseoul.com

U.S. Department of Agriculture

www.usda.gov

USDA Agriculture Exporters Guide

<http://www.fas.usda.gov/gainfiles/200509/146131034.pdf>

USDA Animal Plant and Health Inspection Service (APHIS)

www.aphis.usda.gov

USDA Food and Agricultural Import Regulations and Standards

<http://www.fas.usda.gov/gainfiles/200508/146130525.pdf>

1/20/2006 83

USDA Food Safety and Inspection Service

<http://www.fsis.usda.gov/frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OFO/export/KOREASO.htm>

Foreign Agricultural Service (FAS), U.S. Department of Agriculture (Attaché reports)

www.fas.usda.gov

American Chamber of Commerce Korea

<http://www.amchamkorea.org/about/about.jsp>

U.S. Department of Commerce, Commercial Service Korea

www.buyusa.gov/korea

Department of Commerce, Bureau of Industry and Security

<http://bxa.fedworld.gov/>

Korean Agency for Technology and Standards (KATS)

www.ats.go.kr

Published technical regulations and standards

http://www.ats.go.kr/fm_03/pyojun.asp

Korea Customs Service

<http://www.customs.go.kr/eng/>

Korean Food and Drug Administration (KFDA)

<http://www.kfda.go.kr/>

Korean Laboratory Accreditation Scheme (KOLAS)

www.kolas.go.kr

Ministry of Commerce, Industry, and Energy

<http://english.mocie.go.kr/index.jsp>

National Trade Estimate

http://www.ustr.gov/Document_Library/Reports_Publications/2005/2005_NTE_Report/Section_Index.html

Telecommunications Technology Association (TTA)

www.tta.or.kr